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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,089	10/04/2005	Joachim Hoernes	ROCHE-P003	4169
63049 7590 03/12/2010 BAKER & DANIELS LLP / ROCHE 300 NORTH MERIDIAN STREET SUITE 2700 INDIANAPOLIS, IN 46204				
EXAMINER				
OMCBA, ESSAMA				
ART UNIT		PAPER NUMBER		
3726				
NOTIFICATION DATE		DELIVERY MODE		
03/12/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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### Office Action Summary

**Application No.**

10/552,089

**Applicant(s)**

HOENES ET AL.

**Examiner**

Essama Omgba

**Art Unit**

3726

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 2-10, 12-18 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yuzhakov et al. (US 2002/0168290) in view of Kuhr et al. (US Patent 7,396,334) and Briggs et al. (US 2007/0219462).

With regards to claims 18 and 21-23, Yuzhakov et al. discloses a method for producing combined puncturing and measuring devices for detection of an analyte in liquid comprising a support 8 and a detection element 12 (see abstract and paragraph [0010]), the method comprising forming recesses (spaces between elements 212 in figure 6A) which define puncturing points 212 on one face of a band shape support material, applying a detection element 206, and separating individual puncturing/measuring disposable bodies singly from the band-shaped support material at separating lines (fig. 6A and paragraph [0108]. Although Yuzhakov et al. does not explicitly disclose sterilizing the puncturing points and/or the band-shaped support material, however it is known to sterilize puncturing points of lancet devices at the time of manufacture as attested by Kuhr et al., see column 8, lines 54-62 and column 9, lines 10-11. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have sterilized the puncturing and measuring devices of

Yuzhakov et al., in light of the teachings of Kuhr et al., in order to prevent infection during puncturing of the skin. Regarding the recitation of sealing the puncturing points, such is known in the art as attested by Briggs et al., see paragraphs [00338] and claims 1 and 18. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have sealed the puncturing points when producing the puncturing and measuring device of Yuzhakov et al./Kuhr et al., in light of the teachings of Briggs et al., as is known in the art.

Regarding claim 2, see channel 238 and paragraphs [0104] , [0113] and [0114] of Yuzhakov et al. as well as paragraph [0356] of Briggs et al.

Regarding claims 3-5, see figures 6A-6C.

Regarding claim 6, see channel 238 and paragraph [0082].

Regarding claim 7, see claim 7 of Briggs et al.

Regarding claim 8, see paragraphs [0104] and [0112] of Yuzhakov et al.

Applicant should note that Yuzhakov et al. discloses that any known fabrication process may be used to manufacture the test strips.

Regarding claim 9, see figure 6A.

Regarding claim 10, Applicant should note that it is conventional to ground such puncturing points.

Regarding claims 12, 13 and 16, see paragraph [0116] of Yuzhakov et al. and paragraph [0341] of Briggs et al. Applicant should note that applying different coatings one after the other or simultaneously is well known in the art of coextruding for example.

Regarding claims 14, 15 and 17, see figure 6A of Yuzhakov et al.

Regarding claim 20, applicant should note that the channels in the method of Yuzhakov et al. can be produced by embossing.

3. Claim 7, *in the alternative*, is rejected under 35 U.S.C. 103(a) as being unpatentable over Yuzhakov et al./Kuhr et al./Briggs et al. as applied to claim 2 above, and further in view of Ehrlich (US Patent 2,801,633).

Yuzhakov et al./Kuhr et al./Briggs et al. discloses a method for producing combined puncturing and measuring devices as shown above. Although Yuzhakov et al./Kuhr et al./Briggs et al. does not specifically show the depressions having a depression base with a triangular contour, however it is known to form such depressions with depression bases having triangular, round or oval contour as attested by Ehrlich, see figures 8 and 9. Therefore it would have been obvious to have formed the depressions of the device of Yuzhakov et al./Kuhr et al./Briggs et al. with a depression base having a triangular contour, in light of the teachings of Ehrlich, as a matter of obvious design choice.

4. Claims 11, 19 and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yuzhakov et al./Kuhr et al./Briggs et al. as applied to claims 18 and 21 above, and further in view of Schenk et al. (US Patent 5,397,334).

Yuzhakov et al./Kuhr et al. discloses a method for producing combined puncturing and measuring devices as shown above including a detection device applied to the puncturing/measuring bodies after the puncturing and measuring devices have been sterilized (col. 8, lines 54-62 of Kuhr et al.). Although Yuzhakov et al./Kuhr et al./Briggs et al. does not explicitly disclose providing a soft plastic cover on the

puncturing points of the puncturing devices, however it is known to cover the puncturing points of such devices with a cover in order to preserve the sterility of the puncturing points as attested by Schenk et al., see column 1, lines 54-61 and column 5, lines 31-35, see also claim 10 of Briggs et al. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have provided a cover on the puncturing point of the device of Yuzhakov et al./Kuhr et al./Briggs et al., in light of the teachings of Schenk et al., in order to preserve the sterility of the puncturing point. Regarding the recitation of the cover being made from soft plastic, Applicant should note that it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have made the cover out of any material that was expedient that could preserve the sterility of the puncturing points since it has been held to be within the general skill level of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. *See also Ballas Liquidating Co. v. Allied industries of Kansas, Inc.* (DC Kans) 205 USPQ 331.

### ***Response to Arguments***

5. Applicant's arguments with respect to claims 2-10, 14-18, 20 and 21 have been considered but are moot in view of the new ground(s) of rejection.
6. Applicant's arguments filed November 19, 2009 as they relate to claims 11-13 and 19 have been fully considered but they are not persuasive.

In response to Applicant's argument that the references do not disclose using a soft plastic cover, the examiner submits that it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have made the cover out of any material that was expedient that could preserve the sterility of the puncturing points since it has been held to be within the general skill level of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. *See also Ballas Liquidating Co. v. Allied industries of Kansas, Inc.* (DC Kans) 205 USPQ 331.

In response to Applicant's argument that the references do not teach simultaneously depositing the coatings and the detection elements, the examiner submits that in an obviousness rejection, it is not necessary to find precise teachings in the prior art directed to the specific subject matter claimed because inferences and creative steps that a person of ordinary skill in the art would employ can be taken into account. *KSR Int'l Co. v. Teleflex Inc.* 550 U.S. 398, 418 (2007). If a technique has been used to improve one process, and a person of ordinary skill in the art would recognize that it would improve similar processes in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *See id.* at 417. The examiner maintains that one of ordinary skill in the art would know to simultaneously provide two coating on a substrate.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Essama Omgba whose telephone number is (571) 272-4532. The examiner can normally be reached on M-F 9-6:30, 1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Bryant can be reached on (571) 272-4526. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Essama Omgba/  
Primary Examiner, Art Unit 3726